UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09 663,968	09 19 2000	Ping Yip	24736-2049	4499

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HELLER EHRMAN WHITE & MCAULIFFE LLP
4250 EXECUTIVE SQ
7TH FLOOR
LA JOLLA, CA   92037

EXAMINER
MAHATAN, CHANNING

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 08/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

	Application No.	Applicant(s)
Office Action Summary	09/663,968	YIP, PING
	Examiner	Art Unit	
	Channing S. Mahatan	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _1-45_ is/are pending in the application

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _1-45_ is/are rejected.

7)☒ Claim(s) _2 and 3_ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

    If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All b)☐ Some * c)☐ None of:

        1.☐ Certified copies of the priority documents have been received.

        2.☐ Certified copies of the priority documents have been received in Application No. _____ .

        3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

    a)☐ The translation of the foreign language provisional application has been received.

2)☒ Notice of Draftsperson's Patent Drawing Review (PTO-948).

3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _5 Sheets_

5)☐ Notice of Informal Patent Application

6)☒ Other *Attachment for PTO-948*

DETAILED ACTION

ART UNIT DESIGNATION

The Group and/or Art Unit designated for this application has changed. Applicant is

hereby informed that future correspondence regarding this application should be directed to

Group Art Unit 1631.

OBJECTION BY DRAFTSMAN

Applicant is hereby notified that the required timing for correction of drawings has

changed. See the last 6 lines on the sheet, which is attached, entitled "Attachment for PTO-948

(Rev. 03/01 or earlier)". Due to the above notification Applicant is required to submit drawing

corrections with the time period set for responding to this Office action. Failure to respond to

this requirement may result in abandonment of the instant application or a notice of a failure to

fully respond to this Office action.

CLAIMS UNDER EXAMINATION

Claims herein under examination are claim 1-45.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly
claiming the subject matter which the applicant regards as his invention.

Claims 1-45 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for

failing to particularly point out and distinctly claim the subject matter which applicant regards as

the invention.

Vague and Indefinite

Claim 1 (line 2) and all claims dependent therefrom recite the phrase "data set indicative of the composition" which is vague and indefinite. Applicant can resolve this issue by particularly pointing the criteria/range/value the by which the data set is indicative of the composition. Clarification via clearer claim wording is required.

Claims 1 (line 9), 38 (line 13), 40 (line 11), and all claims dependent therefrom recite the phrase "responsive to removing the residual baseline" which is vague and indefinite. Is locating a probable peak in the corrected data set performed or not; suggested by the phrase "responsive to removing the residual baseline"? Further, it is unclear what applicant is referring to as being responsive; i.e. an immediate response or a response time/action set by some criteria/range/value? Clarification via clearer claim wording is required.

Claims 6 (line 2), 8 (line 2), and all claims dependent therefrom recites the phrase "stage 0" which is vague and indefinite. It is unclear what "stage 0" is/represents. Applicants can resolve this issue by particularly pointing out "stage 0". Clarification via clearer claim wording is required.

Claims 13 (line 2) and all claims dependent therefrom recite the phrase "sparse data set indicative of the denoised data" which is vague and indefinite. Applicant can resolve this issue by particularly pointing the criteria/range/value the by which the sparse data set is indicative of the denoised data. Clarification via clearer claim wording is required.

Claim 19 (line 2) and all claims dependent therefrom confusing recites the phrase "compressing the intermediate data set". Is the intermediate data set compressed after the step

4) or after the step "removing the residual baseline from the intermediate data set to generate a corrected data set" (claim 1, lines 7-8)? Further, if the intermediate data set is compressed, is this data utilized? There is no indication of a compressed intermediate data set in claim 1. Clarification via clearer claim wording is required.

Claim 19 (line 3) and all claims dependent therefrom recites the phrase "data values associated with respective addresses" which is vague and indefinite. It is unclear by what means the data values are associated with respective addresses. Applicant can resolve this issue by particularly pointing out the criteria/range/value, which formulates said association. Clarification via clearer claim wording is required.

Claim 20 (line 2), 21 (line 2), and all claims dependent therefrom recites the phrase "compressed data value" which is vague and indefinite. Applicant defines "compressed data value" (claim 20 (lines 2-3) and 21 (lines 2-4)), however, fails to indicate the purpose/use of "compressed data value" to the instantly claimed invention. It is acknowledged that claim 19 (to which both claims 20 and 21 depend from) includes a step of "compressing the intermediate data set", however, does not proceed to form/identify a new data set with "compressed data values". Clarification via clearer claim wording is required.

Claim 45 is indefinite due to the lack of clarity of the claim language failing to recite a final process step, which agrees back with the preamble. The preamble states that it is "a system for identifying a component in a biological sample", however the claim recites a final step of "calling the composition of the biological sample responsive to the calculated probability". There is no indication that a component in a biological sample is to be identified as resuscitated

step must be recited in a positive, active fashion. The claim does not set forth the conditions/state when the system identifies the component. Clarification of the metes and bounds of the claim is requested via clearer claim wording.

Lack of Antecedent Basis

Claim 12 recites the limitation "threshold factor" in lines 1-2. There is no clear antecedent basis for this limitation in claims 1 and 5-7, which claim 12 depends from.

Claim 15 and all claims dependent therefrom recites the limitation "correcting the baseline" in lines 1-2. There is no clear antecedent basis for this limitation in claim 1, which claim 15 depends from; i.e. no step for correcting the baseline.

Claim 44 recites the limitation "correctly called components" in lines 1-2. There is no clear antecedent basis of this limitation in claims 41 and 43, which claim 44 depends from; i.e. no indication of a correctly called component.

Claims Rejected Under 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 15-18, 38-41, and 45 are rejected under 35 U.S.C. § 102(b) as being anticipated by Green et al. (U.S. Patent No. 5,853,979).

Green et al. describes a method and system to normalize experimental fragment patterns for nucleic acid polymers (Abstract, lines 1-26). A raw fragment pattern (representing positions

obtained from the experimental sample and is conditioned using conventional baseline correction

(instant claims 1 and 15-18) and noise reduction techniques (instant claims 1 and 4) to yield a

clean fragment pattern (Column 3, lines 45-51). The invention is applicable to any data set,

which separates oligonucleotide fragments in space or time; i.e. mass spectrometry (Column 5,

lines 9-18); instant claims 2 and 3. (Column 5, lines 19-46). The inventors illustrate the effect

of background subtraction and band-pass frequency filtration on the appearance of data (Figure 1

and Column 4, lines 19-20). Green et al. describes various techniques to condition the raw

fragment pattern yielding a "clean fragment pattern"; i.e. background subtraction, low frequency

filtration, and high frequency filtration (Column 5, lines 19-46). The inventors then illustrate a

comparison of an experimental nucleotide fragment pattern and a standard nucleotide fragment

pattern between and a standard fragment pattern, allowing for the identification/validation of a

biological sample (Figure 2 and Column 7-8, lines 40-67 and 1-17). Further, the invention is to

be implemented using a computer with a means for receiving raw or clean experimental fragment

patterns and programmed to compare experimental and a standard fragment pattern to obtain a

normalized fragment pattern, aligning the normalized fragment patterns, and evaluating the

nucleic acid sequence of the sample (Column 4, lines 10-15 and Column 16, lines 27-59); instant

claims 38-41, and 45. Thus, Green et al. clearly anticipates the instantly claimed invention.

Claims Rejected Under 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set
forth . . . . of the differences between the subject matter sought to be patented and

Claims 1-12, 15-21, 27, 28, 38-41, and 45 are rejected under 35 U.S.C. § 103(a) as being

unpatentable over Green et al. (U.S. Patent No. 5,853,979) in view of Cai et al.

Green et al. describes a method and system to normalize experimental fragment patterns

for nucleic acid polymers (Refer to § 102(b) rejection; instant claims 1-4, 15-18, 38-41, and 45),

however, Green et al. fails to describe the utilization of wavelet transformation to denoise the

data.

Cai et al. teaches the application of wavelet transformation to denoising analytical data

and evaluates different wavelet transform methods using synthetic data containing white

Gaussian noise (abstract). The authors illustrate the different transform levels of a wavelet

representation (instant claims 5-9); wherein the top graph is a Gaussian function at a signal-to-

noise ratio of 7 (Figure 2 and page 1162, Column 1, lines 1-4); instant claims 27 and 28. Various

threshold criteria (instant claims 10-12) are described that may be applied to wavelet denoising

(page 1162, Column 1, lines 9-16 and pages 1163-1164). Data processing computations were

performed on a computer, wherein all wavelet filter coefficients and some programs were

obtained from a computer package (page 1166, Column 1, lines 22-29). Cai et al. discuss

wavelet packet transform which smooth and further transforms data utilizing wavelet coefficients

at different levels (page 1165, Column 1, lines 6-26). The authors illustrate denoising results by

various denoising methods for HPLC data (Figure 10 and page 1168, Column 2, lines 8-29).

Therefore, it would have been obvious to someone of ordinary skill in the art at the time

of the invention to practice Green et al. (method and system to normalize experimental fragment

patterns for nucleic acid polymers) with Cai et al. (wavelet transformation to denoise analytical

(instant claims 19-21) and noise reduction for smoothing electro-spray mass spectra (instant claims 2 and 3) (page 1161, Column 1, lines 4-8). Additionally, Cai et al. states that wavelet transforms offer a potential means for compressing measurement data and removing unwanted noise from data (page 1169, Column 1, lines 17-20). Thus, one of ordinary skill in the art would be motivated to utilize wavelet transformations to further reduce noise from experimental fragment patterns of nucleic acids since Cai et al. states experimental measurements contain interfering noise, which limits the interpretation of data (page 1161, Column 1, lines 12-17).

Duplicate Claim Objection

Claim 2 is objected to under 37 C.F.R. § 1.75 as being a substantial duplicate of claim 3. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See M.P.E.P. § 706.03(k). Claim 3 defines the data set as one generated by a mass spectrometer, therefore resulting in a spectrometry data set (as in the instant claim 2). Thus, claims 2 and 3 are directed to a spectrometry data set.

Appropriate Correction Is Required.

No Claims Are Allowed.

Examiner Information

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the

1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, William Phillips, whose telephone number is (703) 305-3482 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: August 8, 2002

Examiner Initials: *CSM*

MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).